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Assessing clinical benefit in the treatment of pancreas cancer: gemcitabine compared to 5-fluorouracil.

Burris H, Storniolo AM

Brooke Army Medical Center, Fort San Houston 78234 Texas, USA.

An early study with gemcitabine in pancreas cancer indicated greater relief of disease-related symptoms than expected from the objective tumour response rate. A novel design was created to assess changes in symptomatology prospectively in two studies. The design focuses on typical features seen in patients with advanced pancreas cancer (pain, impaired function, weight loss) and the endpoint is 'clinical benefit response'. Traditional endpoints of objective tumour response and survival were also included. In a randomised study, the clinical benefit response rate for gemcitabine was 24% compared with 5% for 5-fluorouracil (5-FU) (P = 0.0022). The median survival was 5.65 months for gemcitabine compared with 4.41 months for 5-FU (P = 0.0025). The corresponding objective response rates were 5.4% and 0%. Disease stabilised in 39% and 19% of gemcitabine and 5-FU patients, respectively. In a second study of 5-FU-refractory patients, 27.0% of patients were clinical benefit responders. The median survival in this second study was 3.8 months; the objective response rate was 11%, and 30% of patients had stable disease. These trials show that gemcitabine improves disease-related symptoms and survival in patients with pancreas cancer.

Publication Types:

- Clinical trial
- Randomized controlled trial

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